Summary of Safety and Effectiveness
Line Extension to the Hoffmann® II External Fixation System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	December 11, 2000

Device Identification

Proprietary Name:	Hoffmann® II 90° Post
Common Name:	External Fixation Frame Component
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030

Predicate Device Identification

The Hoffmann® II 30° Post was determined substantially equivalent via 510(k) K952730. The Hoffmann® II 30° Posts are used with the Hoffmann® II Multi-Pin Clamps and allow a Hoffmann® II Rod to Rod Coupling to connect to a Hoffmann® II Multi-Pin Clamp. The curved post is used when it is desirable to have the post project from the Hoffmann® II Multi-Pin Clamp at an angle that follows the patient's limb.

Device Description

The Hoffmann® II 90° Post is a modification of the Hoffmann® II 30° Post. The modifications involve changing the bend radius, bend angle to 90° and overall length. The shaft diameter remains the same as well as all other critical geometry.

Intended Use:

This subject component, when used together with the components of the Hoffmann® II External Fixation System and Apex® Pins, creates an external fixation frame construct. The subject device is intended to be used in the construction of external fixation frames to provide stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting.

Statement of Technological Comparison:

Static cantilever beam testing demonstrates the comparable mechanical properties of the subject to the predicate .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2001

Ms. Elizabeth A. Staub
Vice President, Quality Assurance/ Regulatory Compliance/ Clinical Research
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401-1677

Re: K003848
Trade Name: Hoffmann II External Fixation System, 90° Post
Regulatory Class: II
Product Codes: JEC and LXT
Dated: December 11, 2000
Received: December 12, 2000

Dear Ms. Staub:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003848

Device Name: Hoffmann® II 90° Post

Indications For Use:

The Hoffmann® II 90° Post is intended to be used in conjunction with the components of the Hoffmann® II External Fixation System and the Apex™ Half Pins of the Hoffmann® External Fixation System.

This device is used to provide stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casts, or other means of internal fixation. The indications for use of metallic external fixation devices include:

- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003848

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)